

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS**

IN RE PHARMACEUTICAL INDUSTRY
AVERAGE WHOLESALE PRICE LITIGATION

THIS DOCUMENT RELATES TO:

The City of New York v. Abbott Laboratories, Inc., et al.
S.D.N.Y. Case No. 04-CV-06054

County of Albany v. Abbott Laboratories, Inc., et al.
N.D.N.Y. Case No. 05-CV-0425

County of Allegany v. Abbott Laboratories, Inc., et al.
W.D.N.Y. Case No. 05-CV-0236

County of Broome v. Abbott Laboratories, Inc., et al.
N.D.N.Y. Case No. 05-CV-0456

County of Cattaraugus v. Abbott Laboratories, Inc., et al.
W.D.N.Y. Case No. 05-CV-0256

County of Cayuga v. Abbott Laboratories, Inc., et al.
N.D.N.Y. Case No. 05-CV-0423

County of Chautauqua v. Abbott Laboratories, Inc., et al.
W.D.N.Y. Case No. 05-CV-0214

County of Chemung v. Abbott Laboratories, Inc., et al.
W.D.N.Y. Case No. 05-CV-6744

County of Chenango v. Abbott Laboratories, Inc., et al.
N.D.N.Y. Case No. 05-CV-0354

County of Columbia v. Abbott Laboratories, Inc., et al.
N.D.N.Y. Case No. 05-CV-0867

County of Cortland v. Abbott Laboratories, Inc., et al.
N.D.N.Y. Case No. 05-CV-0881

County of Dutchess v. Abbott Laboratories, Inc., et al.
S.D.N.Y. Case No. 05-CV-6458

County of Essex v. Abbott Laboratories, Inc., et al.
N.D.N.Y. Case No. 05-CV-0878

County of Fulton v. Abbott Laboratories, Inc., et al.
N.D.N.Y. Case No. 05-CV-0519

MDL NO. 1456
Civil Action No. 01-12257-PBS

Judge Patti B. Saris

**PLAINTIFFS' OPPOSITION TO
DEFENDANT SANDOZ INC'S
SUPPLEMENTAL
MEMORANDUM OF LAW
REGARDING MULTIPLE
SOURCE GENERIC DRUG
PRODUCTS IN SUPPORT OF
DEFENDANTS' MOTION TO
DISMISS**

County of Genesee v. Abbott Laboratories, Inc., et al.
W.D.N.Y. Case No. 05-CV-00267

County of Greene v. Abbott Laboratories, Inc., et al.
N.D.N.Y. Case No. 05-CV-0474

County of Herkimer v. Abbott Laboratories, Inc., et al.
N.D.N.Y. Case No. 05-CV-00415

County of Jefferson v. Abbott Laboratories, Inc., et al.
N.D.N.Y. Case No. 05-CV-0715

County of Lewis v. Abbott Laboratories, Inc., et al.
N.D.N.Y. Case No. 05-CV-0839

County of Madison v. Abbott Laboratories, Inc., et al.
N.D.N.Y. Case No. 05-CV-00714

County of Monroe v. Abbott Laboratories, Inc., et al.
W.D.N.Y. Case No. 05-CV-6148

County of Nassau v. Abbott Laboratories, Inc., et al.
E.D.N.Y. Case No. 04-CV-05126

County of Niagara v. Abbott Laboratories, Inc., et al.
W.D.N.Y. Case No. 05-CV-06296

County of Oneida v. Abbott Laboratories, Inc., et al.
N.D.N.Y. Case No. 05-CV-0489

County of Onondaga v. Abbott Laboratories, Inc., et al.
N.D.N.Y. Case No. 05-CV-0088

County of Ontario v. Abbott Laboratories, Inc., et al.
W.D.N.Y. Case No. 05-CV-6373

County of Orleans v. Abbott Laboratories, Inc., et al.
W.D.N.Y. Case No. 05-CV-6371

County of Putnam v. Abbott Laboratories, Inc., et al.
S.D.N.Y. Case No. 05-CV-04740

County of Rensselaer v. Abbott Laboratories, Inc., et al.
N.D.N.Y. Case No. 05-CV-00422

County of Rockland v. Abbott Laboratories, Inc., et al.
S.D.N.Y. Case No. 03-CV-7055

County of Schuyler v. Abbott Laboratories, Inc., et al.
W.D.N.Y. Case No. 05-CV-6387

County of Seneca v. Abbott Laboratories, Inc., et al.

W.D.N.Y. Case No. 05-CV-6370

County of St. Lawrence v. Abbott Laboratories, Inc., et al.
N.D.N.Y. Case No. 05-CV-0479

County of Saratoga v. Abbott Laboratories, Inc., et al.
N.D.N.Y. Case No. 05-CV-0478

County of Steuben v. Abbott Laboratories, Inc., et al.
W.D.N.Y. Case No. 05-CV-6223

County of Suffolk v. Abbott Laboratories, Inc., et al.
E.D.N.Y. Case No. 03-CV-12257

County of Tompkins v. Abbott Laboratories, Inc., et al.
N.D.N.Y. Case No. 05-CV-0397

County of Ulster v. Abbott Laboratories, Inc., et al.
N.D.N.Y. Case No. 06-CV-0123

County of Warren v. Abbott Laboratories, Inc., et al.
N.D.N.Y. Case No. 05-CV-0468

County of Washington v. Abbott Laboratories, Inc., et al.
N.D.N.Y. Case No. 05-CV-0408

County of Wayne v. Abbott Laboratories, Inc., et al.
W.D.N.Y. Case No. 05-CV-06138

County of Westchester v. Abbott Laboratories, Inc., et al.
S.D.N.Y. Case No. 03-CV-6178

County of Wyoming v. Abbott Laboratories, Inc., et al.
W.D.N.Y. Case No. 05-CV-6379

County of Yates v. Abbott Laboratories, Inc., et al.
W.D.N.Y. Case No. 05-CV-06172

INTRODUCTION

Sandoz, Inc. and Geneva Pharmaceuticals (hereinafter “Sandoz”)¹ asserts that “plaintiffs concede that New York Medicaid reimbursed pharmacies for many generic drugs identified in the complaints pursuant to formulas that do not refer to AWP (or WAC)” and do not identify the formula that applied to the reimbursement of plaintiffs’ products. Sandoz Brief (“MTD”) at 1, 2. Sandoz says that the asserted failures are fatal to a claim that the New York Medicaid program relied on and was injured by an allegedly fraudulent AWP because no “reliance or causal connection between the alleged fraud and the claimed injuries” has been demonstrated. *Id.* at 2. Sandoz concludes that the consolidated complaint (“CC”) should be dismissed under Rule 12(b) because New York can never show overpayment based on reported AWP’s, and dismissed under 9(b). *Id.* Although Sandoz is not clear on this point, these arguments can only be geared towards those multi-source drugs whose reimbursement is based on the FUL. What Sandoz writes mischaracterizes and ignores relevant portions of the pleadings and is often factually inaccurate. In addition, Sandoz ignores entirely that plaintiffs pled manipulation of the FUL by all multi-source manufacturers and explained how such manufacturers’ failures to report accurate prices resulted in inflated FULs and overcharges to Medicaid. Sandoz’s motion should be denied in its entirety.

ARGUMENT

I. The CC Adequately Alleges How Sandoz’ Price Inflation Schemes Damage Medicaid

In its prior opinions, the Court ruled that Fed. R. Civ. P. 9(b)’s particularity requirements are satisfied where these conditions are met:

¹ Each of the following Defendants joined in the Sandoz this memorandum as to those cases in which it is a party: Abbott Laboratories, Inc., Alpharma, Inc., Barr Laboratories, Inc., Ben Venue Laboratories, Inc., Roxane Laboratories, Inc. Dey, Inc., Dey, L.P., ETHEX Corporation, Ivax Corporation, Ivax Pharmaceuticals, Inc., Par Pharmaceutical, Inc., Par Pharmaceutical Companies, Inc., Mylan Laboratories, Inc. and UDL Laboratories, Inc., Pharmacia Corporation, Greenstone Ltd., Purepac Pharmaceuticals Co., Sisor Inc., Teva Pharmaceuticals USA, Warrick Pharmaceuticals Corp., Watson Pharmaceuticals, Inc., Watson Pharma, Inc., and Wyeth. Thus, this brief provides a detailed response to each and appropriately exceeds the five page limit of CMO #21.

- 1) “[A] spread which [plaintiff possesses] a good-faith basis to calculate”² or, alternatively;
- 2) A detailed overview of the fraudulent scheme that fits the “paradigm described in the complaint” (*In re Pharmaceutical Indust. Average Wholesale Price Litig.*, 307 F.Supp.2d 196, 208 (D.Mass. 2004)(“*Pharm IP*”)); and
- 3) “[W]ith respect to each defendant, 1) the specific drug or drugs that were purchased from defendant, 2) the allegedly fraudulent AWP for each drug and 3) the name of the specific plaintiffs that purchased the drug.” *Id.*

The Counties satisfy these requirements. The Counties plead the fraudulent scheme as generally applicable to all defendants, *including Sandoz*. The CC alleges that Sandoz has reported intentionally false and misleading wholesale price information on which Medicaid reimbursements are based in order to market the spread with the intention of seizing market share from competitors, thereby harming Medicaid by causing it to pay inflated reimbursement prices. CC at ¶ 9, 12. The “spread” is “the difference between the actual acquisition cost of a drug and the amount at which the drug is reimbursed.” *Id.* at ¶ 9.

The Counties plead their reimbursement formulas as applicable to all defendants, including Sandoz. For brand name drugs and for multi-source drugs without FULs, reimbursements are based on AWP. CC at ¶ 86-88, Consolidated Opp. at 1. Multi-source drugs with FULs are reimbursed based on the FUL’s, which in turn are based on the price of the “least costly therapeutic equivalent”. *Id.* Defendants submission of misleading wholesale price information leads to an inflated FUL. The inflated FUL leads to overpayments by the Counties. (See CC at ¶¶ 9, 86, 122, 126, 136), Consolidated Opp. at 1. In short, the pleadings allege which products were reimbursed based on AWP or FUL, that FULs are established based on the lowest reported price for a drug, and that Sandoz, et. al, knew and took advantage of this fact in order to increase market share and to enrich

² In *In re Pharmaceutical Indust. Average Wholesale Price Litig.*, 2004 WL 2387125 at *2 (D.Mass. 2004), the Court held that in the absence of allegations particularizing the circumstances surrounding the price reporting, Suffolk could satisfy 9(b) by alleging a spread which for which it has “a good-faith basis”. See *Id.*, (“[t]he so-called “Suffolk 13” ...insist that the allegations concerning the spread are not particular enough because ... there are no ...allegations (e.g., government investigations or the company's own internal documents) to support a claim of fraudulent pricing.... If there is a good faith basis for calculating a spread, the Court will deny the motion to dismiss”).

itself directly, at the expense of the Counties. *Id.* As these allegations pertain to all defendants, they apply equally to all signatories to Sandoz' MTD.

Thus, plaintiffs have generally plead 1) fraudulent conduct (reporting false and inflated wholesale price information); 2) the causal connection (by showing how the applicable reimbursement formulas were inflated by the fraud); and 3) reliance (by showing the money paid by counties on the basis of these inflated reimbursements). Plaintiffs further provide each NDC at issue, its fraudulent AWP, and its purchase by the Counties. *See* CC, Exh. A, at 58-69.

Plaintiffs added the requisite particularity to these general allegations in reference to Sandoz. Sandoz reported "false and misleading wholesale price information" for its drugs. CC at ¶ 624. Plaintiffs allege that Sandoz knew it could market the spread to increase its market share. *See id.* at ¶ 625. Plaintiffs allege that Sandoz in fact did market its products this way and refer directly to documents wherein Sandoz instructed its employees to market the spread. *See id.* at ¶¶ 625, 628. Finally the Counties set forth those NDCs for which the counties' investigation already have shown Sandoz's pricing to be fraudulently misleading by showing those drugs whose AWPs exceeded market prices by greater than 40%. *See* CC Exh. B-23. The Counties have done likewise for every other defendant who signed on to Sandoz's brief. *See* attached Exhibit A to Counties' Opposition to Sandoz MTD, Columns B, C, and D.

Sandoz argues that plaintiffs "have not alleged, which, if any of Sandoz' products New York Medicaid paid reimbursement on the basis of a reported AWP...[and] [p]laintiffs' theory fails to the extent they purport to state claims for those reimbursements that were not based on AWP." (Sandoz MTD at 3). The preceding section demonstrates contra. Plaintiffs do plead (by category, not drug by drug) 1) the applicable reimbursement formulas for all different types of drug products and 2) the fraudulent scheme being perpetrated under each different reimbursement formula. Sandoz's substantive objection thus reduces itself to: "Without product specific and time-specific allegations

that each of the reimbursements ... was based on an AWP formula, Plaintiffs claim must be dismissed for lack of specificity because plaintiffs have not alleged a causal connection between Sandoz' AWP and their alleged injury." Sandoz MTD at 4.

Sandoz's assertion is twice wrong. First, as shown above, the pleadings allege the applicable reimbursement formula for each drug, the applicable fraudulent scheme, and the requisite particularity as required by this Court's prior opinions. Second, Sandoz fabricates a requirement that the counties "provide product specific and time-specific allegations that each of the reimbursements ... was based on an AWP formula." *Id.* This requirement ignores the courts prior rulings almost entirely. The court flatly stated that counties are not required to plead each "product specific and time-specific allegation" *Pharm III*, 307 F.Supp.2d at 208, ("[W]here the alleged scheme of fraud is complex and far-reaching, pleading every instance of fraud would be extremely ungainly, if not impossible.) There was no requirement that each claim be based on an AWP formula. And plaintiffs have adequately plead the fraudulent scheme for those drugs reimbursed based on the FUL plaintiffs plead that if Sandoz had reported its lower generally available market prices, the FULs for these NDCs would have been lower.

II. Sandoz Makes Inappropriate and Worse Inaccurate Hors De Complaint Statements

As demonstrated above, the Counties' allegations were sufficiently particular even for those drugs that were reimbursed at the FUL. Sandoz's arguments *contra* depend in significant part on mischaracterization. Sandoz writes:

Even a *cursory* review demonstrates that Plaintiffs have not actually alleged that they relied on or were injured by the cited AWP's for the simple reason that **many of the products were reimbursed at the FUL, not an AWP-based formula.**

[]Exhibit B to the Consolidated Complaint states that that the pricing of Sandoz' Albuterol Sulfate 2 mg tablet (100-units), as of December 12, 2000, created a 983.01% spread between the AWP of \$28.05 and the alleged market price of \$2.59. However, since at least November 2000, a FUL of \$.0380 (or \$3.80 per 100-units) has been in place for this drug ... Hence, neither the AWP nor the alleged spread listed for Sandoz' Albuterol Sulfate

2 mg tablet had any effect on New York Medicaid paying reimbursement at the FUL.

Sandoz MTD at 4 (citations omitted, emphasis added).

Sandoz, et al., cannot get the facts right on this. First, defendants state that a FUL of .038 was in place for Albuterol Sulfate 2 mg tablets from “since at least November 2000.” This is incorrect. The FUL for Albuterol Sulfate 2 mg tablets was increased from \$.038 to \$.0477 in March of 2002.³ And Albuterol Sulfate 2 mg tablets were removed from the FUL list in December of 2002.⁴ Thus, at all times since December 2002, Albuterol Sulfate 2 mg tablets have been reimbursed at AWP at inflated prices orders of magnitude greater than the FUL. And Sandoz made the same mistake for the drugs Desipramine HCL 50mg and Perphenazine 8mg Tablet Oral 100. These drugs were only temporarily on the FUL list, then returned to AWP reimbursement.⁵

Sandoz’ complains that plaintiffs did not match the applicable reimbursement formula presented in the body of the complaint to every NDC listed in exhibits A&B. Although this is more than what Fed R. Civ. P. 9(b) requires, plaintiffs have the ability to plead this detail.⁶ Cicala Aff at 2-10, Exh. A hereto. Should the Court so desire, Plaintiffs promptly can amend their complaint and/or the exhibits thereto in this narrow regard to set forth the particular transactional data (NDC by NDC, date by date, and price by price) in support of this statement.

Conclusion

For all the foregoing reasons, the Sandoz Motion to Dismiss should be denied in its entirety.

³ See Changes to FUL transmittal 37, Price Increases, page 7, available at new.cms.hhs.gov/FederalUpperLimits/Downloads/ChangesMadeToTransmittal37.pdf, increasing the FUL for Albuterol Sulfate 2 mg tablets to \$.047.

⁴ See *Id.*, Deleted Drugs, Page 2, stating that Albuterol Sulfate 2 mg tablets have been removed from the FUL list.

⁵ As of 8/1/2002, a FUL was no longer in place for Desipramine HCL 50mg, (see www.cms.hhs.gov/FederalUpperLimits/Downloads/ChangesMadeToTransmittal37.pdf). As of 1/22/2002, a FUL was no longer in place for Perphenazine 8mg Tablet Oral 100. *Id.* Contrary to Sandoz representations, these drugs have been reimbursed at AWP since their removal from the FUL list. See CC at ¶88.

⁶ The Counties are now in possession of pricing information that indicates that approximately 80%⁶ of the Sandoz NDCs that are subject to a FUL in fact have FULs ranging from 100% to 700% above the generally available market prices for those same Sandoz NDCs. (Recall that the FUL is mandated to be only 50% greater than the least costly therapeutic equivalent.) See Exhibit A hereto columns E, F, G, for identical information pertaining to all other defendants who signed on to the Sandoz MTD.

Dated: April 17, 2006.

Respectfully submitted,

**City of New York and all captioned Counties
except Nassau, by**

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SANDOZ REPLY

EXHIBIT A

Supplemental Exhibit A to the Counties' Opposition to Sandoz Motion to Dismiss

	A	B	C	D	E	F	G	H
		CC allegations satisfying 9(b)s particularity requirement in each defendant specific section	CC allegations satisfying 9(b)s particularity requirement in Exhibit A	CC allegations satisfying 9(b)s particularity requirement in Exhibit B	Total NDCs	Number of NDCs subject to a FULL	Number of NDCs subject to a FULL and for which plaintiffs possess pricing data	Percentage of NDCs for which Plaintiffs currently possess pricing data with FULL Acquisition Cost Spreads greater than 100%
1	Defendants who signed onto Sandoz Motion to Dismiss							
2	Abbott Laboratories, Inc.	175, 177-179	p.1-6	B-1	1048	99	37	5%
3	Alpharma, Inc.							
4	Purepac Pharmaceuticals Co.	204, 205	p.6-10	B-3	733	558	237	38%
5	Barr Laboratories, Inc.	274; 275	p.12-15	B-6	696	516	144	27%
6	Ben Venue Laboratories, Inc. (Boehringer)	341; 342; 343	p.23-26	B-10	159	21	11	36%
7	Dey, Inc.	403-409	p.26	B-11	91	49	21	86%
8	Ethex Corporation	464-466	p.29	B-14	142	23	14	57%
9	Greenstone Ltd.	657-659	p.73-79	B-26	96	67	41	10%
10	Ivax Corporation,							
11	Ivax Pharmaceuticals, Inc.	532-533	p.35-47	B-17	1795	1338	316	67%
12	Mylan Laboratories, Inc.							
13	UDL Laboratories, Inc.	610-611	p.52-58	B-22	1045	838	560	58%
14	Par Pharmaceutical, Inc.,							
15	Par Pharmaceutical Companies, Inc.							
16	Pfizer	644-645	p.69-73	B-24	723	585	178	53%
17	Pharmacia Corporation	657-659	p.73-79	B-26	1026	280	133	3%
18	Roxane Laboratories, Inc.	341; 342; 343	p.73-79	B-26	416	69	42	0%
19	Sandoz, Inc.	624; 625; 628	p.23-26	B-10	398	190	76	66%
20	Sicor Inc.		p.58-69	B-23	1294	943	396	55%
21	Teva Pharmaceuticals USA	772-774	p.85-92	B-29	1294	958	496	63%
22	Warrick Pharmaceuticals Corp.	712-713	p.111-114	B-28	96	64	33	73%
23	Watson Pharmaceuticals, Inc.	797-798	p.92-101	B-30	1993	1483	776	60%
24	Wyeth	812-815	p.101-107	B-31	985	426	160	33%